

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the : Meir Rosenberg
Application of

Serial No. : 10/656,973

Filed : September 5, 2003

Entitled : METHOD AND APPARATUS FOR
MANAGING NORMAL PRESSURE
HYDROCEPHALUS

Docket No. : 22719-47 (COD5023USNP)

Confirmation No.: 8809

Group Art Unit: 3761

Examiner: L. R. Deak

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate of Transmission (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being
electronically filed via EFS-Web to: MS Appeal Brief –
Patents, Commissioner for Patents on:

March 23, 2009
Date of Deposit

/Christina M. Sperry/
By: Christina M. Sperry,
Reg. No. 47,106

REPLY BRIEF

This paper is submitted in response to the Examiner's Answer mailed January 22, 2009.
Appellant respectfully requests that the arguments presented below be considered in connection with
this appeal.

I. Introduction

Appellant has appealed the rejection of claims 1-9 and 13-27 (all of the pending claims), and submitted an Appeal Brief on November 4, 2008. The Examiner filed an Answer to the Appeal Brief on January 22, 2009 to which Appellant now responds.

All of the bases for rejection have been addressed in the Appeal Brief, and Appellant submits this Reply Brief only to address the Examiner's "Response to Argument."

II. Saul 915 And Ericson Cannot Be Combined

Rejected independent claim 1 requires providing an implantable shunt system having an adjustable resistance valve for regulating the flow of CSF into and out of a ventricular cavity and a selectively operable external system controller device for communicating remotely via telemetry with the implantable shunt system, and manually reenergizing the implantable shunt system with the system controller device. Similarly, rejected independent claim 17 requires an implantable shunt system having an adjustable resistance valve for regulating the flow of CSF into and out of a ventricular cavity and a selectively operable external system controller device for communicating remotely via telemetry with the implantable shunt system and configured to manually energize the implantable shunt system.

Appellant's Appeal Brief explains that there is no advantage to the Examiner's proposed modification of U.S. Patent Publication No. 2003/0032915 A1 to Saul ("Saul 915") in view of U.S. Patent No. 6,533,733 to Ericson et al. ("Ericson"), thereby providing a reason not to combine the references as proposed by the Examiner. In response, the Examiner argues that:

the advantage derived from combining the teachings of Saul [915] with Ericson is not the mere adjustment of valve pressure and resistance but the ability to *remotely* adjust the valve pressure and resistance without the need for adjusting associated wires and sensors, as taught by Ericson.

Examiner's Answer, p. 7. (Emphasis in original.) The Examiner further asserts that:

[o]ne of ordinary skill in the art at the time of invention could have combined the elements disclosed by Saul 915 and Ericson to yield an apparatus for draining CSF from a patient with a remotely adjustable valve in order to allow adjustment without repeated trips to a care provider or reattachment of wires. Such an advantage comprises a rational reason for the proposed combination absent an express teaching in either of the references.

Examiner's Answer, p. 8.

Appellant disagrees with the Examiner's arguments. There is no reason a person of ordinary skill in the art would modify Saul 915 in view of Ericson to achieve a result which Saul 915 already achieves, adjusting valve pressure and resistance. The Examiner still fails to provide such a reason.

Saul 915 provides that "the controller 32 will be constructed or programmed to open the valve 30 in response to increases in the transient component of patient ICP and to close the valve in response to decreases in the transient component." Saul 915, para. [0033]. This plainly indicates that Saul 915 provides for *automatic* valve opening and closing in response to a transient monitored value. However, the Examiner asserts on page 11 of the Examiner's Answer that Appellant has failed to cite any portion of Saul 915 "that references 'automatic' valve opening and closing."¹ The absence of the word "automatic" in Saul 915 does not negate the fact that the valve in Saul 915 does in fact automatically open and close based on algorithms programmed into the controller. *See* Saul 915, para. [0035]. After all, the entire purpose of Saul 915 is to use an implanted system to automatically control valve opening and closing to control intracranial pressure based on a transient component that can require valve opening or closing at any given unpredictable time. *See* Saul 915, Abstract and para. [0024] and [0033].

The valve in Saul 915 *already* provides for valve adjustment with a preprogrammed controller. There is simply no need for remote adjustment of the valve pressure or resistance as disclosed by Ericson when the controller in Saul 915 is specifically programmed to respond to transient pressure conditions on a continuous or frequent basis. *See id.*, para. [0010]. A person skilled in the art would simply have no reason or motivation to remotely adjust the valve on a continuous or frequent basis when Saul 915's controller is already provided to do just that without the need for adjusting any wires or sensors or for repeatedly visiting a care provider.

Moreover, the Examiner appears on page 10 of the Examiner's Answer to suggest *replacement* of Saul 915's implanted valve control with Ericson's remote monitoring because Ericson's "communication apparatus is capable of performing in the time intervals required by Saul 915" such that Saul 915's principle of operation need not be changed to be modified in view of

¹ Appellant also notes that paragraph [0033] of Saul 915 has previously been cited by Appellant with respect to automatic valve opening and closing in addition to paragraphs [0010] to [0012] of Saul 915. *See, e.g.*, Appeal Brief, pages 3 and 10.

Ericson.² However, even if the Board presumes Ericson to be so capable and Saul 915 so modifiable without changing its principle of operation or making Saul 915 unsatisfactory for its intended purpose, despite Saul 915 clearly being directed to an implantable continuous or frequent monitoring system, there is no reason or motivation, outside of Appellant's disclosure, to replace Saul 915's implantable control system with Ericson's remote control system when Saul 915 already achieves the same purpose without the need to redesign and restructure Saul 915's system to implement Ericson's remote monitoring.

Appellant's Appeal Brief also explain that the Examiner's rejection requires modifying Saul 915 in view of Ericson in such a way that requires a substantial reconstruction and redesign, thus presenting a further reason why the rejection should be reversed. In response to this point the Examiner argues that:

[s]ince Saul 915 suggests a connection with an external device during a recharging event, it is the position of the Examiner that combining Saul 915 with Ericson does not require a substantial redesign of the Saul 915 device.

Examiner's Answer, p. 10.

The Examiner fails to appreciate that the ability of Saul 915 to communicate with an external device for recharging purposes does not change the fact that the controller in Saul 915 that controls the opening and closing of the valve based on preprogrammed parameters and algorithms would have to be substantially redesigned and reconstructed to accommodate the Examiner's proposed modification in view of Ericson. As discussed above and in the Appeal Brief, Saul 915's entire design relies on an implantable control system that monitors pressure and opens and closes the implanted valve as transient conditions change. This self-contained implantable control system would have to be substantially redesigned and reconstructed to be replaced with Ericson's externally charged system. Modifying Saul 915 to facilitate manual energization would require removing the existing internal controller and providing Saul 915 with a selectively operable external system controller device that is configured to manually energize the system. As Saul 915's entire design relies on an implantable shunt and an implantable shunt control system that can monitor transient

² The Examiner states on page 10 of the Examiner's Answer that because of Ericson's disclosed "periodic" monitoring and Saul 915's disclosed "frequent" monitoring that "it is the position of the Examiner that the proposed combination *does change* the principle of operation of the Saul 915 device." (Emphasis added.) Appellant presumes that this is a typographical mistake and that the Examiner meant to disagree with Appellant and state that the Examiner's proposed modification of Saul 915 *does not change* the principle of operation of Saul 915.

changes and make programmed valve adjustments accordingly without external intervention, removing these implantable features responsive to transient changes would be a large, complicated undertaking requiring substantial reconstruction and redesign.

Even if Saul 915's system was not replaced by Ericson's remote system but somehow supplemented by it, Saul 915's transient monitoring and accordant valve movement would still have to be substantially reconstructed and redesigned. At the very least, Saul 915 would have to be substantially reconstructed and redesigned to accommodate interruptions by a selectively operable external system controller, which would not even be providing any additional monitoring or valve control benefits over the self-contained effective monitoring system already provided by Saul 915.

III. Conclusion

For the reasons noted above, as well as those argued in Appellant's Appeal Brief, Appellant submits that the pending claims define patentable subject matter.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 22719-47.

Respectfully submitted,

Dated: March 23, 2009

/Christina M. Sperry/
Christina M. Sperry, Reg. No. 47,106
Attorney for Appellant
NUTTER McCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2699
Telephone: (617) 439-2394
Facsimile : (617) 310-9394